



<b>FORM PTO-1449 (Modified)</b> US Patent and Trademark Office <b>INFORMATION DISCLOSURE CITATION</b> in an Application (Use several sheets if necessary)	Docket No. <b>52071.4</b>	Application No. <b>09/955,259</b>
	Applicant <b>Nestor Annibali</b>	
	Filing Date <b>September 12, 2001</b>	Group Art Unit <b>1636</b>

**U.S. PATENT DOCUMENTS**

Examiner Initial	Ref. No.	Document Number	Date of Patent	Name	Class	Subclass	Filing Date if Appropriate
MKG	A1	4,343,898	8/10/82	Markussen			
	A2	4,431,740	2/14/84	Bell et al.			
	A3	4,916,212	4/10/90	Markussen et al.			
	A4	5,460,954	10/24/95	Lee et al.			
	A5	5,618,913	4/8/97	Brange et al.			
↓	A6	5,663,291	9/2/97	Obermeier et al.			

**U.S. PATENT APPLICATION PUBLICATION DOCUMENTS**

Examiner Initial	Ref. No.	Document Number	Date of Publication	Name	Class	Subclass	Filing Date if Appropriate
	A7						

**FOREIGN PATENT DOCUMENTS**

Examiner Initial	Ref. No.	Document Number	Date of Publication	Country	Class	Subclass	Translation	
							Yes	No
not considered, not in English	B1	0 046 979	3/10/82	EPO				No
MKG	B2	0 055 945	7/14/82	EPO				
MKG	B3	0 195 691	9/24/86	EPO				
not considered, not in English	B4	0 291 863	11/23/88	EPO				No

**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent Pages, etc.)

MKG	C1	Brange et al., "Monomeric insulins obtained by protein engineering and their medical implications", Nature, vol. 333, pp.679-682, 1988.					
	C2	Castellanos-Serra et al., "Expression and folding of an interleukin-2-proinsulin fusion protein and its conversion into insulin by a single step enzymatic removal of the C-peptide and the N-terminal fused sequence", FEBS Letters 378, pp. 171-176, 1996.					
	C3	Cowley et al., "Expression, purification and characterization of recombinant human proinsulin", FEBS Letters 402, pp.124-130, 1997.					
	C4	Chan et al., "Biosynthesis and periplasmic segregation of human proinsulin in <i>Escherichia coli</i> ", Proc. Natnl. Acad. Sci USA vol. 78, no. 9, pp.5401-5405, 1981.					
	C5	Chance et al., "Chemical, Physical, and Biologic Properties of Biosynthetic Human Insulin", Diabetes care, vol. 4, no. 2, pp. 147-154, 1981.					
	C6	Chance et al., "The Production of Human Insulin Using Recombinant DNA Technology and a New Chain Combination Procedure", Diabetes care 4:147; pp. 721-728, 1981.					
↓	C7	Chang et al., "Human insulin production from a novel mini-proinsulin which has high receptor-binding activity", Biochem. J. 329, pp. 631-635, 1998.					



C8	Cregg et al., "Functional Characterization of the Two Alcohol Oxidase Genes from the Yeast <i>Pichia pastoris</i> ", Molecular and Cellular Biology, vol. 9, no.3, pp. 1316-1323, 1989.
C9	Cregg et al., "Recent Advances in the Expression of Foreign Genes in <i>Pichia pastoris</i> ", Bio/Technology vol. 11, pp. 905-910, 1993.
C10	Di Donato et al., "A Method for Synthesizing Genes and cDNAs by the Polymerase Chain Reaction", Analytical biochemistry, 212, pp. 291-293, 1993.
C11	Frank et al., "The Production of Human Proinsulin and its Transformation to Human Insulin and C-Peptide", Proceedings of the 7 <sup>th</sup> Am Peptide Chem. Symposium, pp. 729-738, 1981.
C12	Gagnon et al., "Large-Scale Process Development for Hydrophobic Interaction Chromatography, Part 1: Gel Selection and Development of Binding Conditions", Biopharm 8, pp. 21-27, 1995.
C13	Goeddel et al., "Expression In <i>Escherichia coli</i> of chemically synthesized genes for human insulin", Proc. Natnl. Acad. Sci. USA vol. 76, no. 1, pp.106 -110, 1979.
C14	Jensen et al., "Scintigraphic Studies in-Rats", Diabetes, vol. 40, pp. 628-632, 1991.
C15	Katsoyannis et al., "Studies on the Synthesis of Insulin from Natural and Synthetic A and B Chains. I. Splitting of Insulin and Isolation of the S-Sulfonated Derivatives of the A and B Chains", Am. Chem. Soc. Vol. 6, no. 9, pp. 2635-2655, 1967.
C16	Kemmler et al., "Studies on the Conversion of Proinsulin to Insulin", The J. of Biol. Chem. vol. 246, no. 22, pp. 6786-6791, 1971.
C17	Kristensen et al., "Alanine Scanning Mutagenesis of Insulin", The J. of Biol. Chem. vol. 272, no. 20, pp. 12978-12983, 1997.
C18	Kroeff et al., "Production Scale Purification of Biosynthetic Human Insulin by Reversed-Phase High-Performance Liquid Chromatography", J. of Chromatography, 461, pp. 45-61, 1989.
C19	Rose et al., "Rapid preparation of human insulin and insulin analogues in high yield by enzyme-assisted semi-synthesis", Biochem. J. 211, pp. 671-676, 1983.
C20	Smith et al, "Heterologous Protein Secretion from Yeast", Science, vol. 229, pp. 1219-1224, 1985.
C21	Steiner et al., "The Spontaneous Reoxidation of Reduced Beef and Rat Proinsulins", Biochemistry: Steiner and Clark, vol. 60, pp. 622-629, 1968.
C22	Thim et al., "Secretion and processing of insulin precursors in yeast", Proc. Natnl. Acad. Sci. USA vol. 83, pp. 6766-6770, 1986.
C23	Veenhuis et al., "The Significance of Peroxisomes in the Metabolism of One-Carbon Compounds in Yeasts", Advances in Microbial Physiology, vol. 24, 81 pgs. 1983.
C24	Wang et al., "Studies on Receptor Binding Site of Insulin: The Hydrophobic B12VAL Can be Substituted by Hydrophilic THR", Biochem. and Molecular Biol. International vol. 39, no. 6 pp.1245-1254, 1996.
✓ C25	Wollmer et al., "Reduction/Reoxidation Studies with Cross-Linked Insulin Derivatives", Hoppe-Seyler's Z. Physiol. Chem. Bd. 355, pp. 1471-1476, 1974.

EXAMINER

Michelle K. Golee

DATE CONSIDERED

12/27/05

EXAMINER: Initial if references considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.